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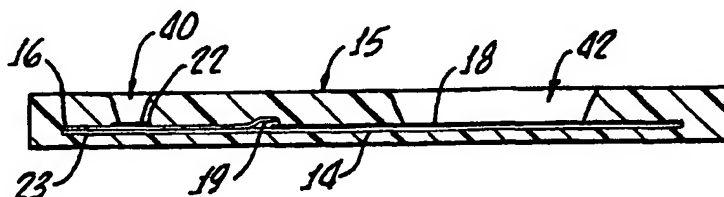
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(54) Title: **DEVICE AND PROCESS FOR LATERAL FLOW SALIVA TESTING**



(57) Abstract: A method and device (10) are provided for performing diagnostic testing of an oral fluid specimen. A lateral flow test strip (14) having a sample portion (16), a test portion (18) and a pad (22) made of glass fiber material.

DEVICE AND PROCESS FOR LATERAL FLOW SALIVA TESTING

The present invention generally relates to devices and processes for collection and testing of fluid specimens, and more specifically relates to a device and process for
5 lateral flow testing of oral fluid, for example saliva.

Unlike other forms of fluid specimens such as blood or urine, collection of oral fluid, for example saliva, for diagnostic purposes is complicated by many factors, for example, the low volumes of salivary fluid secreted into the oral cavity, the relatively high viscosity thereof, and the diverse anatomic dispersion of the salivary glands. Most
10 techniques for collection involve the use of capillary tubes, suction into micropipettes, chewing on paraffin or foam, and/or aspiration from the mouth into polypropylene syringes.

Conventional, commercially available lateral flow test strips (i.e. nitrocellulose strips) have long been used for diagnostic testing of bodily fluids such as urine. These
15 devices are inexpensive and produce reliable results for many applications. These same test strips however are not conventionally used for testing oral fluids such as saliva. It is known that when saliva is applied to a sample pad of a commercially available urine testing lateral flow test strip, the saliva sample does not run. It is believed that this is due to the relatively high concentrations of mucin and other viscous, proteinaceous materials
20 in the specimen.

In addition, testing of salivary specimens has not been extensively developed. Until relatively recently, blood and urine samples were the primary fluids used for testing for disease as well as for evidence of substance abuse. However, it is known that human saliva carries lymphocytes, plasma cells and immunoglobulins that are directly related to
25 the immunoglobulins found in the blood. In addition, saliva carries immunoglobins that are believed to be peculiar to saliva, for example, the antibody known as secretory IgA. Because of the association between immunoglobulins of the blood and saliva, as well as the occurrence of secretory IgA, antigen-antibody tests have been conducted on salival fluid to assess the value of such tests as screening tools for disease.

U.S. Patent No. 5,933,614 to Cesarczyk describes a Sample Collection Method with Extraction Sleeve. The device is designed for collecting saliva or urine samples using an absorbent, elongate foam member secured in a hollow tube with one portion extending therefrom. The foam member is used to absorb a fluid specimen. The foam member and hollow tube are slidably mounted within a flexible sleeve to cover the foam member as well as provide a means for extracting the fluid from the foam by exerting pressure on the sleeve to compress the foam member to release the fluid. According to Cesarczyk, the device provides an aseptic, easy to use device for collecting a fluid sample such as saliva.

The present invention provides a device and method for diagnostic testing of a saliva sample which overcomes the disadvantages of the prior art, and offers advantages, for example convenience and economy, typically associated with lateral flow test strip devices used for blood and urine tests.

SUMMARY OF THE INVENTION

Accordingly, a method and device are provided for diagnostic testing of an oral fluid, such as saliva or other proteinaceous fluid specimen.

The device generally comprises a housing including well means for receiving a fluid specimen, and testing means, at least partially encased within the housing, for enabling diagnostic testing of the fluid specimen received in the well means. The testing means includes a diagnostic test strip including a sample portion and a test portion for visually indicating test results and test validity.

Advantageously, the device further comprises means for disassociating proteinaceous material from the fluid specimen, for example a membrane or pad having deposited thereon a salt or other known mucinolytic substance known to break down and lower the viscosity of mucin-containing fluids. The pad is preferably comprised of a glass fiber matrix which provides means for filtering the disassociated proteinaceous matter and other particulate material from the specimen. These features of the present

invention function to facilitate migration of an originally viscid, mucin containing fluid specimen, such as saliva, without any pretreatment steps. The device allows convenient and rapid testing of a relatively small saliva sample without any need to pre-treat the saliva in order to enable its migration along the test strip.

5 The salt pad may be positioned to overlay a portion of the sample portion of the test strip. The test strip is encased within the housing such that the salt pad is in fluid communication with the well means.

 The present invention further includes a process for lateral flow saliva testing, generally comprising the steps of providing a lateral flow test strip having a sample
10 portion and a test portion, providing a pad having a material capable of disassociating proteinaceous materials in an oral fluid, for example a salt, positioning the pad along the sample portion of the lateral flow test strip, depositing an oral fluid specimen on the pad positioned on the lateral flow test strip, and allowing proteinaceous materials in the specimen to substantially disassociate from the specimen to facilitate migration of the
15 specimen into the test portion of the lateral flow test strip as a relatively mucin-free specimen.

Brief Description of the Drawings

20 The device will be more readily understood with respect to the following detailed description when considered in conjunction with the accompanying drawings of which:

 Figure 1 shows a perspective view of a device, in accordance with the present invention, for lateral flow testing of oral fluid such as saliva, the device including a lateral flow test strip encased within a housing;

25 Figure 2 shows a cross-sectional view of the device, taken along line 2-2 of Figure 1; and

 Figure 3 shows a top view of the lateral flow test strip of the device shown in Figure 1.

Detailed Description

Turning now to the Figures, a device 10 for lateral flow saliva testing, in accordance with the invention is shown. The device 10 generally includes a lateral flow test strip 14 encased within a housing 15. Similar to conventional lateral flow test strips, the strip 14 includes a sample pad portion 16 and a test portion 18. The device 10 will be described in greater detail hereinafter.

A process, in accordance with the present invention, for lateral flow testing of saliva or other proteinaceous fluid specimen generally includes the step of providing the lateral flow test strip 14, for example made of a nitrocellulose membrane or other suitable material. The test strip 14 includes a conjugate pad 19 having a suitable detector reagent deposited thereon, and capture zones 20 having suitable capture reagents deposited thereon for indicating presence of a target analyte in the specimen sample and, preferably, an indication of test validity. Reagents may be selected to target analytes found specifically in saliva. Process steps for applying the reagents to the test strip are well known in the art, and may include spraying or jetting the reagents onto the nitrocellulose membrane material.

The process in accordance with the invention further comprises the steps of providing a fiber pad 22 (see Figure 2) having deposited thereon a material capable of disassociating proteinaceous materials in an oral fluid. One suitable material is salt, or sodium chloride. The salt may be deposited on the fiber pad 22 by solution evaporation or other suitable means. The fiber pad 22 is positioned and affixed to the sample portion 16 of the lateral flow test strip 14.

The fiber pad 22 may comprise a fiber matrix material having randomly distributed fibers which create a tortuous path of nominally rated size. Preferably, the fiber pad comprises a die-cut portion of a commercially available glass fiber material having a thickness of about 0.0080 inches. After the salt has been deposited on the glass fiber material, the material is cut, for example in a disc shape with a diameter of about 0.1875 inches.. The glass fiber salt disc 22 is then placed on the sample portion 16 of the

lateral flow test strip 14. Although a disc shape is shown and described, it is to be appreciated that other shapes and sizes of glass fiber pads are also possible. The glass fiber disc 22, sample pad 16, conjugate pad 19 and adjacent nitrocellulose test portion 18 may be affixed to a support backing 23 and placed in the housing 15.

- 5 In one embodiment of the invention, the sample portion 16 of a conventional lateral flow test strip 14 is replaced with a glass fiber sample pad, or is modified to include an additional glass fiber layer. The glass fiber sample pad may be made of the same, commercially available glass fiber material described hereinabove.

- 10 For testing a saliva specimen using the example shown, a saliva specimen is applied to the glass fiber salt pad 22. The salt pad 22 breaks down mucin substances in the specimen sample which are subsequently filtered by the glass fibers in the salt pad 22 as well as in the underlying glass fiber sample pad 16 as the specimen migrates toward the lateral flow membrane 14. The specimen sample passes through the conjugate pad 19 where a chemical reaction begins if the analyte is present in the specimen. The specimen
15 sample then passes into the capture zones 20 and the test can be read.

- It is to be understood that the fiber pad 22 effectively facilitates migration of the specimen into the test portion 18 of the lateral flow test strip 14 by both breaking down the proteinaceous material in the specimen and filtering the specimen. More particularly, the salt in the salt pad 22 breaks down the proteinaceous materials in the specimen which
20 are then separated from the less viscous components of the specimen by the glass fiber matrix in the sample pad 16. Thus, after passing through the salt and glass fiber material, the specimen in effect remains as a relatively mucin and particulate free specimen that flows freely and is readily absorbed by the nitrocellulose strip 14.

- Advantageously, the process in accordance with the invention requires no
25 specimen pre-treatment procedure. Accordingly, multiple test strips 14 may be prepared in advance, packaged and reserved for future uses. A saliva specimen may be extracted from a subject person and immediately and directly deposited on the salt pad with a pipette or sponge. The salt in the salt disc 22 will cause the proteinaceous materials to separate from the sample, leaving a more freely flowing, lower viscosity sample that can

be readily absorbed by, and can migrate along, the strip. Any large, proteinaceous particles in the specimen are filtered out of the specimen by the glass fiber material of the pad 22. The relatively mucin and particulate free sample is then able to migrate along the strip, effectively moving the antibody-marker agents along the strip, and producing a
5 reliable test result in the test results portion 18.

Turning now specifically to Figure 1, the device 10 for lateral flow testing of a saliva sample is shown as including well means 40 for receiving a saliva specimen by means of a sponge or pipette (not shown). The lateral flow test strip 14 having the salt pad 22 as described above may be positioned in the housing such that the salt pad 22 is
10 visible through the well 40 as shown. The test portion 18 is visible through a window 42 defined in the housing 15 as shown. The housing may be made of molded plastic or other suitable material.

Although there has been hereinabove described a process and device for lateral flow saliva testing, in accordance with the present invention, for the purpose of
15 illustrating the manner in which the invention may be used to advantage, it will be appreciated that the invention is not limited thereto. Accordingly, any and all modifications, variations, or equivalent arrangements which may occur to those skilled in the art should be considered to be within the scope of the invention as defined in the appended claims.

What is claimed is:

- 5 1. A method for performing diagnostic testing of an oral fluid specimen, the method comprising the steps of:
- providing a lateral flow test strip having a sample portion and a test portion;
- providing a pad having a material capable of disassociating proteinaceous
- 10 materials in an oral fluid;
- positioning the pad on the sample portion of the lateral flow test strip;
- depositing an oral fluid specimen on the pad positioned proximate the sample end of the lateral flow test strip; and
- allowing proteinaceous materials in the specimen to substantially
- 15 disassociate from the specimen to facilitate migration of the specimen into the test portion of the lateral flow test strip as a relatively mucin-free specimen.
2. The method according to claim 1 wherein the pad comprises a glass fiber pad.
- 20 3. The method according to claim 1 wherein the material capable of disassociating comprises a salt.
4. The method according to claim 1 wherein the material is a salt and the step of providing a pad includes the step of evaporating a salt solution on the pad.
- 25 5. The method according to claim 4 wherein the pad comprises a glass fiber pad.
6. The method according to claim 1 further comprising the step of placing a filter member over the sample portion of the lateral flow test in order to filter out

particulate material from the specimen prior to allowing the specimen to migrate along the test strip.

7. The method according to claim 6 wherein the filter member comprises a glass
5 fiber filter member.

8. A device for diagnostic testing of oral fluid such as saliva, the device comprising:

a housing including well means for receiving a fluid specimen;
10 testing means, including an absorbent lateral flow test strip, encased within the housing, for enabling diagnostic testing of the fluid specimen received in the well means; and
fiber pad means, in fluid communication with the well means and the test strip, for disassociating proteinaceous material from the fluid specimen and filtering
15 particulate material from the fluid specimen.

9. The device according to claim 8 wherein the fiber pad means comprises a salt pad.

20 10. The device according to claim 8 wherein the fiber pad means comprises a glass fiber pad.

11. The device according to claim 8 wherein the fiber pad means comprises a glass fiber pad having a salt deposited thereon.

25 12. The device according to claim 8 wherein the fiber pad means comprises a glass fiber pad including and evaporated salt solution.

13. A device for diagnostic testing of oral fluid such as saliva, the device

comprising:

testing means, including an absorbent lateral flow test strip having a sample portion and a test portion, for enabling diagnostic testing of the fluid specimen received on the sample portion;

5 means, comprising a salt deposit in fluid communication with the sample portion, for disassociating particulate proteinaceous material from the fluid specimen; and

fiber pad means, disposed on the lateral flow test strip, for filtering the particulate material from the fluid specimen to facilitate migration of the fluid specimen from the sample portion to the test portion.

10

14. The device according to claim 13 wherein the fiber pad means comprises a glass fiber membrane.

AMENDED CLAIMS

[received by the International Bureau on 1 October 2001 (01.10.01);
original claims 1-14 replaced by new claims 1-14 (3 pages)]

1. A method for performing diagnostic testing of
5 an oral fluid specimen, the method comprising the steps
of:

providing a lateral flow test strip having a
sample portion and a test portion, said test portion
including a detector reagent for diagnostic testing
10 of the fluid specimen;

providing a pad having a material capable of
disassociating proteinaceous materials in an oral
fluid;

positioning the pad on the sample portion of
15 the lateral flow test strip in a portion enabling the
disassociation of proteinaceous material before entering
said sample portion;

depositing an oral fluid specimen on the pad
positioned proximate the sample end of the lateral flow
20 test strip; and

allowing proteinaceous materials in the
specimen to substantially disassociate from the specimen
to facilitate migration of the specimen from the sample
portion and into the test portion of the lateral flow
25 test strip as a relatively mucin-free specimen.

2. The method according to claim 1 wherein the
pad comprises a glass fiber pad.

30 3. The method according to claim 1 wherein the
material capable of disassociating comprises a salt.

4. The method according to claim 1 wherein the material is a salt and the step of providing a pad includes the step of evaporating a salt solution on the pad.

5

5. The method according to claim 4 wherein the pad comprises a glass fiber pad.

6. The method according to claim 1 further comprising the step of placing a filter member over the sample portion of the lateral flow test in order to filter out particulate material from the specimen prior to allowing the specimen to migrate along the test strip.

7. The method according to claim 6 wherein the filter member comprises a glass fiber filter member.

8. A device for diagnostic testing of oral fluid such as saliva, the device comprising:

20 a housing including well means for receiving a fluid specimen;

testing means, including an absorbent lateral flow test strip, encased within the housing, for enabling diagnostic testing of the fluid specimen received in the well means; and

25 fiber pad means, in fluid communication with the well means and the test strip, for disassociating proteinaceous material from the fluid specimen and filtering particulate material from the fluid specimen.

30

9. The device according to claim 8 wherein the fiber pad means comprises a salt pad.

10. The device according to claim 8 wherein the fiber pad means comprises a glass fiber pad.

11. The device according to claim 8 wherein the
5 fiber pad means comprises a glass fiber pad having a salt deposited thereon.

12. The device according to claim 8 wherein the fiber pad means comprises a glass fiber pad including and
10 evaporated salt solution.

13. A device for diagnostic testing of oral fluid such as saliva, the device comprising:

testing means, including an absorbent lateral
15 flow test strip having a sample portion and a test portion, for enabling diagnostic testing of the fluid specimen received on the sample portion;

means, comprising a salt deposit in fluid communication with the sample portion, for disassociating
20 particulate proteinaceous material from the fluid specimen; and

fiber pad means, disposed on the lateral flow test strip, for filtering the particulate material from the fluid specimen to facilitate migration of the fluid
25 specimen from the sample portion to the test portion.

14. The device according to claim 13 wherein the fiber pad means comprises a glass fiber membrane.

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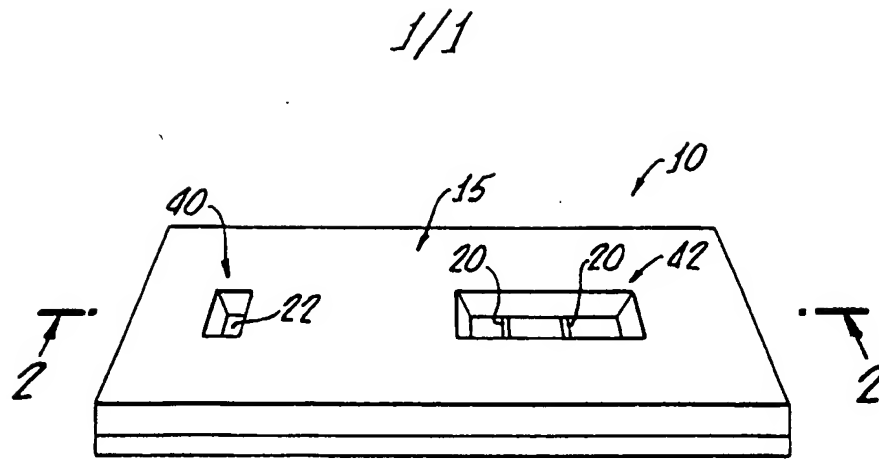


FIG. 1.

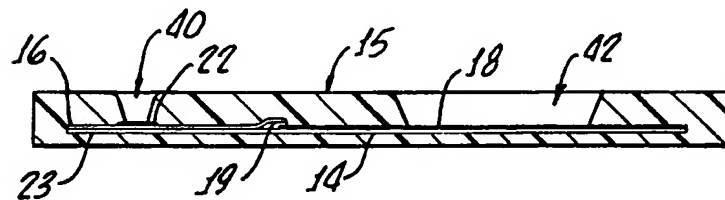


FIG. 2.

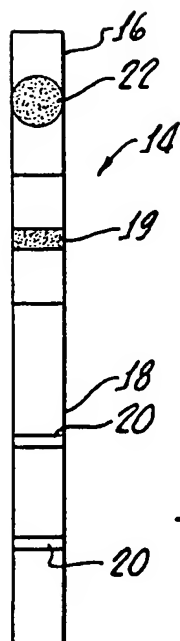


FIG. 3.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/11527

A. CLASSIFICATION OF SUBJECT MATTER		
IPC(7) : G01N 33/48 US CL : 422/61		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) U.S. : 422/61, 58, 56; 436/164, 166, 175-178		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched none		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) none		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,075,078 A (OSIKOWICZ et al) 24 December 1991, see column 9 line 63 and columns 15-16	1-14
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* *A* *E* *L* *O* *P*	Special categories of cited documents: document defining the general state of the art which is not considered to be of particular relevance earlier document published on or after the international filing date document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) document referring to an oral disclosure, use, exhibition or other means document published prior to the international filing date but later than the priority date claimed	*T* *X* *Y* *Z* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art document member of the same patent family
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